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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,891	07/06/2000	James McArthur	40567	6712

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Steven B Kelber Esq
Piper Rudnick LLP
1200 19th Street N W
Washington, DC 20036

EXAMINER	
YU, MISOOK	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/610,891	MCARTHUR ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2004 and 04 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-40 and 44-59* is/are pending in the application.

4a) Of the above claim(s) *48-59* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-40 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on 05/04/2004, and the supplemental amendment filed on 06/04/2004 are acknowledged.

Claims 35- 40 are amended, and claims 44-59 are new. Claims 35-40, and 44-59 are pending. Claims 35-40, 44-47 are under consideration with this Office action.

Claims 48-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) from the examination because the claims are drawn to method of using the cells in the composition of the product claims.

The examined invention i.e. drawn to a composition comprising the cells and the newly presented invention, drawn to method of using the cells are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as to express a protein.

This application contains claims 48-59 drawn to a non-elected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

Specification, Maintained

The specification remains objected because the trademark GVAX is not be accompanied by the generic terminology. Adding the generic terminology for the trademark GVAX at its first occurrence would obviate this objection.

Claim Rejections - 35 USC § 112, Withdrawn

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendment.

The rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is also withdrawn in view of the amendment.

Claim Rejections - 35 USC § 102, Withdrawn

The rejection of claims under 35 U.S.C. 102(b) as being anticipated by Dranoff, et al. (US Pat. 5,637,483, June. 10 1997) is withdrawn since US Pat. 5,637,483 no longer anticipates the amended claims.

The rejection of claims under 35 U.S.C. 102(a) as being anticipated by Hiserdodt, et al., (WO 98/04282, 1998) is withdrawn since US Pat. 5,637,483 no longer anticipates the amended claims.

The Following Are New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 35-39, and 44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanda et al., J Urol. 1994 Mar;151(3):622-8, in view of Savarese et al., Prostate. 1998 Feb 1;34(2):80-91, and further in view of Thomas et al., Hum Gene Ther. 1998 Apr 10;9(6):835-43.

The claims are interpreted as drawn to **composition per se** comprising a proliferation-incompetent cell vaccines engineered to secrete certain GM-CS, wherein the cell is selected from the three cultured prostate cancer cell line cells i.e. LnCap, PC3, or DU145.

The primary reference (Sanda teaches that vaccine composition comprising irradiated prostate cancer cells (i.e. proliferation-incompetent) genetically engineered to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF) is effective for treating anaplastic, hormone refractory prostate cancer. The primary reference does not teach LnCap, PC3, or DU145.

However, the secondary reference (Savarese et al.) teach that LnCap, PC3, or DU145 are well known prostate cell lines and also teach how to culture those cells at page 81. Neither the primary reference nor the secondary reference teaches why one

of skill in the art would be motivated to make and use irradiated (i.e. proliferation-incompetent) prostate established cell line cancer cells genetically engineered to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF).

However, the tertiary reference (Thomas et al.) teach that whole tumor cell vaccines engineered to secrete certain GM-CSF induce potent systemic immune responses and expanding primary autologous human tumor cells have been used in clinical trials but have been found impractical due to the technical difficulty of routinely expanding primary autologous human tumor cells to the numbers required for vaccination, making the generalization of autologous vaccines impractical. GM-CSF-transduced allogeneic vaccines induce systemic antitumor immunity, and suggests allogeneic whole tumor cell vaccine approach might be a good idea.

Therefore, it would have been obvious to make and use composition comprising proliferation-incompetent LnCap, PC3, or DU145 cells engineered to express GM-CSF with a reasonable expectation of success given that LnCap, PC3, or DU145 cells could be obtained from a commercial vendor as taught by the secondary reference and making a proliferation-incompetent cells or genetic engineering to secrete human granulocyte-macrophage colony-stimulating factor (GM-CSF) had been known well before the effective filing date of the instant application as taught by the primary reference. One of ordinary skill in the art would have been motivated to make and use the instantly claimed invention, given that using already established cells are more practical than expanding primary cells as taught by the tertiary reference, and allogeneic vaccine also works.

As for the limitation a prostate tumor-associated antigens of 250, 160, 150, 31 kD, 26 kD, or 14 kD appears to be the consequence of administering the instantly claimed composition into a patient as taught by the instant specification at Figs. 2-7.

Therefore, the limitation is considered as an intended use and is not given patentable weight for purposes of comparing the claims with the prior art. The claims read on the composition *per se*. Furthermore, with regards to claims 44-47 in which optimum parameters and/or control measurements are claimed, it is well within the level of ordinary skill in the art to adjust optimum concentrations of each components for specific intended uses. See In re Kronig, 190 USPQ 425.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey C Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MISOOK YU, Ph.D.
Examiner
Art Unit 1642